Response to Claim Rejections under 35 USC § 112

The following is an excerpt from Example 7:

"The following procedure is a method for manufacturing a dry chemistry test strip (DCD), for the determination of anti-HIV in a test sample.

Filter paper is impregnated with the following solutions and dried at 25 degree C.:

Solution 1

30.2 G PIPES (1,4-Piperazinediethanesulfonic acid)

0.05 Units/mL beta-Galactosidase/HIV antigen (enzyme conjugated to the HIV antigen)

add to 900 mL D.I. water, mix, adjust pH to 6.8, Q.S. to 1000 mL

Solution 2

0.01 M 5-bromo-6-chloro-3-indoxyl-beta-D-galactopyranoside (Magenta- beta-D-Gal)

1 mL (0.1%) DMSO

dissolve in 900.0 mL distilled water, mix, and Q.S. to 1000 mL."

The Examiner has clearly stated that the following is not enough information for an individual skilled in the art. The applicant does not agree. My daughter (17 years old a junior in high school) was handed this formula in our labs and it took her about an hour before both solutions (1 & 2) were fully dissolved in solution and ready for application. She is a bright kid (honors student, etc.) but I would not put her in the field of one skilled in the art. In other words, this novel invention has been explained to such a degree that an individual off the streets (short of being retarded (nothing against retarded people)) could manufacture this. The Examiner could be talking about anyone who has not graduated from the University of South Florida and that might actually qualify as not skilled in the art. If an affidavit is required to validate this please state so in the next office action.

To further explain the question on page 3, 1st paragraph of the Office Action dated 09/09/03 with regards to the color development. Beta-Galactosidase is an enzyme. Which will react readily with 5-bromo-6-chloro-3-indoxyl-beta-D-galactopyranoside to produce a purple color (e.g. no HIV antibody, lots of color will be produced, **inverse** reaction). If there is HIV antibody present in the sample being tested the antibody will bind to the beta-Galactosidase/HIV antigen enzyme conjugate and prevent the Beta-Galactosidase part of the conjugate from reacting with 5-bromo-6-chloro-3-indoxyl-beta-D-galactopyranoside to produce a color reaction, thus, no color produced. I know now this all seems novel, complex, yet quite simple, hopefully this explains the enzyme activity and color development or lack there of.

With reference to the color chart. The color chart as explained in multiple places in the specification would be made with a series of standard solutions of HIV antibody from 0 to 10 fmol/L or greater/less. The chart can vary dependent upon the usage or amounts of standards desired. The color of the chart will go from colored (purple) blocks (0 fmol/L HIV antibody) to no color in the color blocks (10 fmol/L0). Now the applicant admits that no advanced teachings or explanation is needed to make a color chart. The 10 fmol/L of reference is the cutoff used in our own labs here using this novel, secret and proprietary method for HIV screening, of course we also have to fall back on the antiquated ELISA and Western Blot methods for confirmation. See the attached links:

1. Am J Pathol -- Clayton et al. 159 (5): 1933
   ... observed in Ghost (3) cell Bob cells with 15 **fmol/L** gp120 IIIB (F ... ng/ml MIP-1 , or MIP-1ß, and **10** ng/ml ... Although **HIV** IIIB is an X4 or T lymphocyte-trophic virus ...
   ajp.amjpathol.org/cgi/content/full/159/5/1933
2. Clinical Chemistry -- Wedemeyer et al. 48 (9): 1398
   ... range of **10** amol/L to 1 **fmol/L**, including the ... sample-handling devices can process 9–**10** samples/min ... P, Albert J, Lundeberg J. Quantification of **HIV**-1 using ...
   www.clinchem.org/cgi/content/full/48/9/1398 -
   More pages from this site

Please notice the reference to **15 fmol/L** reference, etc. The fmol/L is just a unit of measure. I can provide more reference to this if necessary.

The applicant would be glad to provide an affidavit form of the following results:

Table 1:								
	HIV-1 EIA			Western Blot			Present Art	
N	Neg	Pos		Neg	Pos		Neg	Pos
1		Y			Y			Y
2		Y			Y			Y
3	N				Y			Y
4		Y			Y			Y
5		Y			Y			Y
6		Y			Y			Y
7	N			N			N	
8	N			N			N	
9	N			N			N	
10	N				Y			Y
11		Y			Y			Y
12		Y			Y			Y
13		Y			Y			Y
14		Y			Y			Y
15		Y			Y			Y
16		Y			Y			Y
17	N			N			N	
18	N			N			N	
19	N			N			N	
20	N			N			N	

N=20

Correlation (r): Present Art to Western Blot 100%

Present Art to EIA 95%

This data from Sciteck Clinical Laboratories overcomes any rejections with regards to Carpenter and Ray, not to forget it also overcomes the lack of guidance issue, etc.

Conclusion

For all of the above reasons, applicant submits that the specification and properly limited claims are in proper form, and that the claims all define patentably and clearly. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Conditional Request For Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully Submitted,

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_____ Applicant Pro Se _____

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Certificate of mailing: I certify that on the date below this document and referred attachments, if any, will be deposited with the US Postal service as first class mail in and envelope addressed to: " Commissioner for Patents ,P.O. Box 1450, Alexandria, VA 22313-1450.

Date:02/09/04 _____

signed Jack V. Smith